In the Claims

Please cancel claims 4, 6, 15, and 25 without prejudice and amend claims 1, 2, 5, 7, 8, 11, 13, 16, 19, 20, 22, 23, 26, 29, 30, and 34-36 as follows. For the Examiner's convenience, the pending claims are included herein with claims not amended at this time being marked "Reiterated."

1. (Twice Amended) An immunomodulating composition causing transient transfection for use in treating or preventing [an] autoimmune [disorder] diabetes comprising a nucleic acid construct encoding at least one epitope from [a] at least one self-antigen and a biological response modifier in a pharmaceutically acceptable carrier.

2. (Amended) The composition of claim 1, wherein the autoimmune [disorder] diabetes is [selected from the group consisting of multiple sclerosis (MS), rheumatoid arthritis, systemic lupus erythematosus,] type I diabetes[, scleroderma, myasthenia gravis and ulcerative colitis].

3. (Reiterated) The composition of claim 1, wherein the epitope is derived from insulin B-chain.

5. (Amended) The composition of claim 1, wherein the construct includes a plasmid [backbone].

7. (Amended) The composition of claim [6] 1 wherein the biological response modifier is selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

8. (Amended) The composition of claim [6] 1 wherein the biological response modifier is wherein the biological response modifier is selected from the group consisting of [IL-l (alpha or beta), IL-2, IL-3,] IL-4, [IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, GM-CSF, M-CSF, G-CSF, LIF, LT, TGF-beta,] gamma-IFN [(or alpha or] beta-IFN[), TNF-alpha, BCGF, CD2, ICAM] MIP-b, and any combination thereof.

9. (Reiterated) The composition of claim 1, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the at least one epitope or the biological response modifier.

10. (Reiterated) The composition of claim 9, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

11. (Twice Amended) A method for treating or preventing autoimmune [disorder] diabetes in a subject having or at risk of having the disorder comprising administering to the subject an immunomodulatory effective amount of a nucleic acid construct encoding at least one epitope from [a] at least one self-antigen in a pharmaceutically acceptable carrier, wherein transient expression of the epitope in the subject generates a positive regulatory immune response, thereby treating or preventing the [disorder] diabetes.

12. (Reiterated) The method of claim 11, wherein the subject is a human.

13. (Amended) The method of claim 11, wherein the autoimmune [disorder] diabetes is [selected from the group consisting of multiple sclerosis (MS), rheumatoid arthritis, systemic lupus erythematosus,] type I diabetes[, scleroderma, myasthenia gravis and ulcerative colitis].

14. (Reiterated) The method of claim 11, wherein the epitope is derived from insulin B-chain.

16. (Amended) The method of claim 11, wherein the construct includes a plasmid [backbone].

17. (Reiterated) The method of claim 11, further comprising administering to the subject a nucleic acid sequence encoding a biological response modifier.

18. (Reiterated) The method of claim 17, wherein the biological response modifier is selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

19. (Amended) The method of claim 17, wherein the biological response modifier is selected from the group consisting of [IL-1 (alpha or beta), IL-2, IL-3,] IL-4, [IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, GM-CSF, M-CSF, G-CSF, LIF, LT, TGF-beta,] gamma-IFN [(or alpha or] beta-IFN[), TNF-alpha, BCGF, CD2, ICAM] MIP-b, and any combination thereof.

20. (Twice amended) The method of claim [11] 17, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the at least one epitope and/or the biological response modifier.

21. (Reiterated) The method of claim 20, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

Sub C6

22. (Twice Amended) A method for inducing a regulatory immune response in a subject having or at risk of having [an] autoimmune [disorder] diabetes comprising administering to the subject, an immunomodulatory effective amount of a nucleic acid construct encoding at least one epitope from [a] at least one self-antigen in a pharmaceutically acceptable carrier, wherein transient expression of the [epitope] nucleic acid construct in the subject generates a positive regulatory immune response.

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23. (Amended) The method of claim 22, wherein the autoimmune [disorder] diabetes is [selected from the group consisting of multiple sclerosis (MS), rheumatoid arthritis, systemic lupus erythematosus,] type I diabetes[, scleroderma, myasthenia gravis and ulcerative colitis].

24. (Reiterated) The method of claim 22, wherein the epitope is derived from insulin B-chain.

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26. (Amended) The method of claim 22, wherein the construct includes a plasmid [backbone].

27. (Reiterated) The method of claim 22, further comprising a nucleic acid sequence encoding a biological response modifier.

28. (Reiterated) The method of claim 27, wherein the biological response modifier is selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

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29. (Twice Amended) The method of claim 27, wherein the biological response modifier is selected from the group consisting of [IL-1 (alpha or beta), IL-2, IL-3,] IL-4, [IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, GM-CSF, M-CSF, G-CSF, LIF, LT, TGF-beta,] gamma-IFN [(or alpha or] beta-IFN[), TNF-alpha, BCGF, CD2, ICAM]MIP-b, and any combination thereof.

B1D cancel

30. (Amended) The method of claim [22] 27, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the epitope and/or the biological response modifier.

31. (Reiterated) The method of claim 30, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

32. (Reiterated) The method of claim 11, wherein a single administration of the nucleic acid construct is effective to treat or prevent the disorder.

33. (Reiterated) The method of claim 22, wherein a single administration of the nucleic acid construct is effective to induce the regulatory immune response.

B1 Sub IC9

34. (Amended) The method of claim 11, wherein the positive immune response comprises induction of T-cells reactive to the [autoantigen] at least one epitope.

Sub C9

35. (Amended) The method of claim 11, wherein the positive immune response comprises induction of Th2 lymphocytes reactive to the [autoantigen] at least one epitope.

36. (Amended) The method of claim 11, wherein the positive immune response comprises induction of non-pathogenic or suppressor Th lymphocytes reactive to the [autoantigen] at least one epitope.